

Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA *et al.*, :
ex rel. MARY BIXLER WOOD, :
: Plaintiffs, : 14 Civ. 4958 (ER)
: :
v. :
: Defendants. :
-----x
UNITED STATES OF AMERICA, :
ex rel. MARY BIXLER WOOD, :
: Plaintiff-Intervenor, :
: :
v. :
: CAREFUSION CORPORATION, :
: :
Defendant. :
-----x

STIPULATION AND ORDER OF SETTLEMENT AND PARTIAL DISMISSAL
AS TO DEFENDANT CAREFUSION CORPORATION

WHEREAS, this Stipulation and Order of Settlement and Dismissal (“Stipulation”) is entered into by and among plaintiff the United States of America (the “United States” or “Government”), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York; the relator Mary Bixler Wood (“Relator”), by Relator’s authorized representatives; and defendant CareFusion Corporation (“Defendant” or “CareFusion,” and together with the Government and Relator, the “Parties”), by its authorized representatives;

WHEREAS, in or about July 2014, the Relator filed a complaint under the *qui tam* provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, against Defendant and several other entities (“Relator Complaint”). The Relator Complaint alleges that Defendant violated the FCA (and corresponding state and local laws) by, among other things, selling medical devices that it had purchased from Instrumed International, Inc. (“Instrumed”), a subsidiary of Align Technologies, Inc. (“Align”), to hospitals and other health care providers for use in medical procedures for which claims for reimbursement were submitted to federal health care programs, while knowing that the devices were not approved or cleared for marketing by the United States Food and Drug Administration (“FDA”) pursuant to the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, and were not exempt from the FDCA’s premarket approval or clearance requirements as “pre-amendment devices” (*i.e.*, devices that were, among other things, legally marketed prior to the May 28, 1976, effective date of the Medical Device Amendments of 1976);

WHEREAS, the Government alleges that from 2007 to 2014 (the “Covered Period”), Defendant (1) purchased medical devices from Instrumed that Instrumed claimed qualified as “pre-amendment devices” and, thus, were exempt from the FDCA’s premarket approval or clearance requirements, (2) knew or recklessly disregarded that the devices did not in fact qualify as “pre-amendment devices,” and (3) sold those devices to hospitals and other health care providers for use in medical procedures for which claims for reimbursement were submitted to Medicare and Medicaid. The conduct described in this Paragraph is the “Covered Conduct” for purposes of this Stipulation;

WHEREAS, contemporaneous with the filing of this Stipulation, the Government is filing a Notice of Election to Partially Intervene in the above-referenced *qui tam* action, with respect to the Covered Conduct;

WHEREAS, Defendant intends to enter into separate settlement agreements with certain states impacted by the Covered Conduct (collectively, the “States”) to resolve claims asserted by the States for the Covered Conduct (the “State Agreements”), and has agreed to pay a total of \$478,460.08 to the States pursuant to the State Settlements;

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against Defendant by the Government and in the Relator Complaint, for the Covered Conduct;

NOW, THEREFORE, upon the Parties’ agreement IT IS HEREBY ORDERED that:

TERMS AND CONDITIONS

1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court’s exercise of personal jurisdiction over each of them.
2. Defendant admits, acknowledges and accepts responsibility for the following conduct:
 - a. Devices, as defined in 21 U.S.C. § 321(h), are subject to regulation by the FDA. Before certain devices can be marketed, they must be approved or cleared by the FDA, pursuant to Section 510(k) of the FDCA. However, if a device qualifies as a “pre-amendment device,” it is exempt from the Section 510(k) requirements.
 - b. For a manufacturer such as Instrumed to claim that a particular device qualifies for the pre-amendment status exemption, the manufacturer must be able to

demonstrate, among other things, that the manufacturer itself had legally marketed the device in the United States prior to May 28, 1976, and that the device had not been significantly changed or modified since then.

- c. During the Covered Period, Instrumed sold devices for which Instrumed (i) had not obtained approval or clearance from the FDA to market pursuant to Section 510(k), (ii) was relying on the pre-amendment status exemption from the Section 510(k) requirements to market, but (iii) lacked the required evidence to demonstrate that the devices qualified for the pre-amendment status exemption.
- d. During the Covered Period, CareFusion purchased devices from Instrumed that Instrumed wrongly claimed qualified for the pre-amendment status exception, and then sold those devices to hospitals and other health care providers. Some of the devices were used in procedures for which providers submitted claims for reimbursement to federal health care programs.
- e. During the Covered Period, Instrumed provided CareFusion with the evidence on which it was relying to justify its claim that the above-referenced devices qualified for the pre-amendment status exemption. That evidence — which consisted of excerpts from a catalogue issued by the devices' original manufacturer, not Instrumed, and an affidavit from an Instrumed employee — was insufficient.
- f. After the FDA issued a warning letter to Instrumed in 2014 and Instrumed issued recall notices for the devices at issue, CareFusion ceased selling and distributing the devices.

3. Defendant shall pay to the Government within fourteen (14) business days of the Effective Date (defined below in Paragraph 26) the sum of \$2,821,539.92 plus interest, which shall be compounded annually at a rate of 2.87% accruing from November 20, 2018, to December 21, 2018 (the “Settlement Amount”) in accordance with instructions to be provided by the Financial Litigation Unit of the United States Attorney’s Office for the Southern District of New York. Of the Settlement Amount, \$1,410,769.96, plus 50% of the accrued interest, constitutes restitution to the United States.

4. Defendant agrees to cooperate fully and truthfully with the United States’ investigation of individuals and entities not released in this Stipulation, including but not limited to Avalign, Instrumed, or any of Avalign’s other subsidiaries or corporate predecessors, successors or assigns. Upon reasonable notice, Defendant shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendant further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation that it has undertaken, or that has been performed by another on its behalf, relating to its relationship with Avalign, Instrumed or any of Avalign’s other subsidiaries or corporate predecessors, successors or assigns.

5. Subject to the exceptions in Paragraphs 9 and 14 below (concerning excluded claims and bankruptcy proceedings), and conditioned upon Defendant’s full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases Defendant, including its subsidiaries and

corporate predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812, and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Defendant from liability of any kind.

6. Defendant fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendant has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, or agents related to the Covered Conduct and the United States' investigation, prosecution and settlement thereof.

7. Conditioned on Defendant's timely payment of the full Settlement Amount pursuant to Paragraph 3 above, the Relator, for the Relator and Relator's heirs, successors, attorneys, agents, and assigns, releases Defendant, including its subsidiaries and corporate predecessors, successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the Relator has against Defendant related to or arising from the Relator Complaint; provided, however, that nothing in this Stipulation releases any claims against any other defendant in the Relator Complaint; provided further that nothing in this Stipulation shall preclude Relator from seeking to recover Relator's reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d); and provided further that Relator's

agreement to this release is not a concession by Relator that any of Relator's claims against Defendant extending beyond the Covered Conduct are not well founded.

8. In consideration of the execution of this Stipulation by the Relator and the Relator's release as set forth in Paragraph 7 above, Defendant, including its subsidiaries, predecessors, and corporate successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, release the Relator and Relator's successors, heirs, assigns, attorneys, and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Defendant has against Relator related to or arising from the Relator Complaint; provided, however, that Defendant's agreement to this release is not an admission by Defendant of liability to any of Relator's claims against Defendant extending beyond the Covered Conduct.

9. Notwithstanding the releases given in Paragraph 5 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

- a. any liability arising under Title 26, United States Code (Internal Revenue Code);
- b. any criminal liability;
- c. except as explicitly stated in this Stipulation, any administrative liability, including but not limited to the suspension and debarment rights of any federal agency; mandatory or permissive exclusion from Federal health care programs (as defined in 42 U.S.C. §1320a-7b(f)) under 42 U.S.C. §1320a-7(a) (mandatory exclusion) or 42 U.S.C. §1320a-7(b) (permissive exclusion); suspension or debarment pursuant to 2 C.F.R. Part 376; or actions pursuant to,

or otherwise consistent with, 42 C.F.R. § 52.9, 45 C.F.R. §§ 75.207- 75.208, or 45 C.F.R. §§ 75.371-75.375;

- d. any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. any liability based upon obligations created by this Stipulation; and
- f. any liability of individuals.

10. Defendant shall be in default of this Stipulation if Defendant fails to make the required payment set forth in Paragraph 3 above on or before the due date for such payment, or if it fails to comply materially with any other term of this Stipulation that applies to it (“Default”). The Government shall provide written notice to Defendant of any Default in the manner set forth in Paragraph 25 below. Defendant shall then have an opportunity to cure the Default within ten (10) calendar days from the date of delivery of the notice of Default. In the event that a Default is not fully cured within ten (10) calendar days of the delivery of the notice of Default (“Uncured Default”), interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance of the Settlement Amount, beginning ten (10) calendar days after mailing of the notice of Default. In the event of an Uncured Default, Defendant shall agree to the entry of a consent judgment in favor of the United States against Defendant in the amount of the Settlement Amount as attached hereto as Exhibit A. The United States may also, at its option, (a) rescind this Stipulation and bring any action against the Defendant for any and all claims described in Paragraph 5 above; (b) seek specific performance of this Stipulation; (c) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing Defendant by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Defendant shall

not contest any offset imposed or any collection undertaken by the Government pursuant to this Paragraph, either administratively or in any Federal or State court. In addition, Defendant shall pay the Government all reasonable costs of collection and enforcement under this Paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation pursuant to this Paragraph, Defendant shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

11. The Relator and Relator's heirs, successors, attorneys, agents, and assigns shall not object to this Stipulation; Relator agrees and confirms that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

12. Defendant waives and shall not assert any defenses Defendant may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such criminal prosecution or administrative action.

13. Defendant represents and warrants that it has reviewed its financial situation, that it is currently not insolvent as such term is defined in 11 U.S.C. § 101(32) and that it reasonably believes that it shall remain solvent following payment to the Government of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Stipulation, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Defendant, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in

fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Defendant was or became indebted to on or after the date of this Stipulation, within the meaning of 11 U.S.C. § 548(a)(1).

14. If within 91 days of the Effective Date of this Stipulation or any payment made under this Stipulation, Defendant commences any case, action, or other proceeding under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors or a third party commences any case, action, or other proceeding under any law related to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking an order for relief of Defendant's debts, or seeking to adjudicate Defendant as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Defendant or for all or part of Defendant's assets, Defendant agrees as follows:

- a. Defendant's obligations under this Stipulation may not be avoided pursuant to 11 U.S.C. § 547, and Defendant shall not argue or otherwise take the position in any such case, action, or proceeding that (i) Defendant's obligations under this Stipulation may be avoided under 11 U.S.C. § 547; (ii) Defendant was insolvent at the time this Stipulation was entered into; or (iii) the mutual promises, covenants, and obligations set forth in this Stipulation do not constitute a contemporaneous exchange for new value given to Defendant.
- b. If any of Defendant's obligations under this Stipulation are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the Government, at its option,

may rescind the release in this Stipulation and bring any civil and/or administrative claim, action, or proceeding against Defendants for the claims that would otherwise be covered by the release in Paragraph 5 above. Defendant agrees that (i) any such claim, action, or proceeding brought by the Government would not be subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) as a result of the case, action, or proceeding described in the first sentence of this Paragraph, and Defendant shall not argue or otherwise contend that the Government’s claim, action, or proceeding is subject to an automatic stay; (ii) Defendant shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any claim, action, or proceeding that is brought by the Government within 60 calendar days of written notification to Defendant that the release has been rescinded pursuant to this Paragraph, except to the extent such defenses were available on July 2, 2014; and (iii) the Government has a valid claim against Defendant in the amount of the Settlement Amount and the Government may pursue its claim in the case, action, or proceeding described in the first sentence of this Paragraph, as well as in any other case, action, or proceeding.

- c. Defendant acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Stipulation.
15. Defendant agrees to the following:
 - a. Unallowable Costs Defined: All costs (as defined in the Office of Management and Budget (“OMB”) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published at 2 C.F.R. §§ 200 *et*

seq.; the Department of Health and Human Services adoption of the OMB Guidance provided at 45 C.F.R. § 75, subpart E *et seq.*; the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47 where applicable; or otherwise as specified by federal statutes, regulations or the terms and conditions of a Federal award) incurred by or on behalf of Defendant, including its present or former officers, directors, employees, and agents in connection with:

- (1) the matters covered by this Stipulation;
- (2) the United States' audit(s) and civil investigation(s) of matters covered by this Stipulation;
- (3) Defendant's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with matters covered by this Stipulation (including attorneys' fees);
- (4) the negotiation and performance of this Stipulation; and
- (5) any payment Defendant makes to the United States pursuant to this Stipulation and any payment Defendant may make to the Relator, including expenses, costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendant, and Defendant shall not charge

such Unallowable Costs directly or indirectly to any contracts with the United States.

- c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Defendant shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs (as defined in this Paragraph) included in payments previously sought by Defendant from the United States. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. Any payments due shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States, including the Department of Justice and/or the affected agencies, reserves its right to audit, examine, or re-examine Defendant's books and records and to disagree with any calculation submitted by Defendant or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Defendant, or the effect of any such Unallowable Costs on the amounts of such payments.
- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. This Stipulation is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity except as otherwise provided herein.

17. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, nothing in this Stipulation shall preclude the Relator from seeking to recover Relator's expenses or attorneys' fees and costs from Defendant, pursuant to 31 U.S.C. § 3730(d).

18. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

19. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties.

21. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

22. This Stipulation is binding on Defendant's successor entities.

23. This Stipulation is binding on the Relator's successors, transferees, heirs, and assigns.

24. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

25. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

Monica Folch
Sharanya Mohan
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Email: monica.folch@usdoj.gov
sharanya.mohan@usdoj.gov

TO DEFENDANT:

John T. Bentivoglio
Jennifer L. Bragg
Elizabeth L. Berry
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
Email: john.bentivoglio@skadden.com
jennifer.bragg@skadden.com
elizabeth.berry@skadden.com

26. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the "Effective Date").

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: New York, New York

April 23 2019

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By:

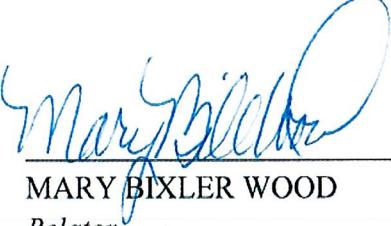


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monica.folch@usdoj.gov
Attorneys for the United States of America

RELATOR

Dated: February 15, 2019
February 15, 2018 *Mary Bixler Wood*

By:


MARY BIXLER WOOD
Relator

Dated: _____, _____
February 15, 2018

HARTER SECREST & EMERY LLP

By:


BRIAN M. FELDMAN
1600 Bausch & Lomb Place
Rochester, NY 14604
Tel.: (585) 232-6500
Attorneys for Relator

DEFENDANT

Dated: Washington, District of Columbia
December 18, 2018

SKADDEN, ARPS, SLATE, MEAGHER &
FLOM LLP

By:



JOHN T. BENTIVOGLIO
JENNIFER L. BRAGG
ELIZABETH L. BERRY
1440 New York Avenue, N.W.
Washington, D.C. 20005
Tel: (202) 371-7560
Attorneys for Defendant

SO ORDERED:

HON. EDGARDO RAMOS
UNITED STATES DISTRICT JUDGE

Dated: _____, 2018

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----x
UNITED STATES OF AMERICA *et al.*, :
ex rel. MARY BIXLER WOOD, :
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UNITED STATES OF AMERICA, :
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: Plaintiff-Intervenor, :
: :
v. :
: :
CAREFUSION CORPORATION, :
: :
Defendant. :
-----x

CONSENT JUDGMENT

Upon the consent of plaintiff the United States of America and defendant CareFusion Corporation (“CareFusion”), it is hereby

ORDERED, ADJUDGED and DECREED: that plaintiff the United States of America is awarded judgment in the amount of \$2,821,539.92 as against CareFusion, as well as post-judgment interest at the rate of 12% per annum compounded daily.

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: New York, New York
April 23, 2019

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By:


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Attorneys for the United States of America

DEFENDANT

Dated: Washington, District of Columbia
December 18, 2018

SKADDEN, ARPS, SLATE, MEAGHER &
FLOM LLP

By:



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JENNIFER L. BRAGG
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Tel: (202) 371-7560
Attorneys for Defendant

SO ORDERED:

HON. EDGARDO RAMOS
UNITED STATES DISTRICT JUDGE

Dated: _____, 2018